Self-Monitoring of Blood Glucose: are they IN CONTROL

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CHAPTER 5

EFFECTS OF SELF-MONITORING OF GLUCOSE IN BLOOD OR URINE ON DIABETES-SPECIFIC DISTRESS AND SELF-EFFICACY IN PATIENTS WITH NON-INSULIN TREATED TYPE 2 DIABETES

Submitted

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Abstract

Objective Self-monitoring of glucose is widely considered as an important tool in diabetes self-management. Concerns about a possible negative impact of self-monitoring on Quality of Life (QoL) and self-care behaviours have been raised. We investigated the effects of self-monitoring of glucose in blood or urine, on diabetes-specific distress and self-efficacy, compared to control in non-insulin treated patients with type 2 diabetes.

Design/setting One-year, three-armed randomised controlled trial in diabetes care systems in the Netherlands.

Participants 181 patients with type 2 diabetes treated with diet or oral hypoglycaemic agents, mean (SD) Hba1c of 58 (15) mmol/mol, age 61.5 (7.8) years and median (q1, q3) diabetes duration of 5 (3, 9) years.

Interventions Standardized diabetes care with education as the control group (n=62), self-monitoring of blood glucose (SMBG) (n=60) or self-monitoring of urine glucose (SMUG) (n=59) with instructions how to interpret results and what actions to take.

Main outcome measures Between group differences in diabetes-specific distress (PAID) and self-efficacy (CIDS-2) after 12 months.

Results There were no statistically significant between-group differences in changes in PAID and CIDS-2 after 12 months. Mean difference in PAID over 12 months between SMBG and control, adjusted for baseline levels was 2.56 points (95% CI -0.12 to 5.24) and between SMUG and control 0.81 points (95% CI -2.10 to 3.72). Mean difference in CIDS-2 over 12 months between SMBG and control, adjusted for baseline levels was 0.49 points (95% CI -2.65 to 3.64) and between SMUG and control -1.43 points (95% CI -4.95 to 2.09).

Conclusion The study demonstrated that self-monitoring of glucose in blood or urine did not affect diabetes-specific distress in moderately controlled non-insulin treated type 2 diabetes patients.

Introduction

Having diabetes demands large efforts, including prolonged adherence to a specific diet, physical activity and medication. Not being able to comply with these demands can lead to diabetes-specific emotional distress, which, in turn, may negatively influence adherence to self care behaviours, compromise glycaemic control and affect quality of life [1]. Effective diabetes self-management can protect against factors responsible for emotional distress and may positively influence quality of life and presence of depressive symptoms [1-3].

Self-monitoring of blood glucose (SMBG) is widely considered as an important tool in diabetes self-management and commonly recommended for non-insulin treated patients with type 2 diabetes [4;5]. Self-monitoring and its feedback are considered as a tool to improve comprehension of the effects of diet and physical activity on blood glucose levels.

Whether glucose self-monitoring effectively contributes to glycaemic control in type 2 diabetes patients not treated with insulin is the subject of an ongoing debate [6-12]. As part of this debate, concerns of a possible association of self-monitoring of glucose with increased worries and depressive symptoms have been raised. This could especially be the case when self-monitoring outcomes are incongruous with expectations, or when proposed actions to target (unexpected) outcomes are unclear. Experiencing such negative emotions may discourage patients from correct self-care behaviour and may be a cause of suboptimal glycaemic control [3]. Thus, it is important to provide patients with adequate education so they can have full understanding of the self-monitoring processes and required (re)actions. Our theoretical framework originating from behavioural research, explains that the processes of monitoring, getting feedback, (re)acting and evaluating may lead to enhanced beliefs of control [13;14] and self-efficacy [15] and may increase active participation of the patient in its self-care management. To date, studies reporting associations of self-monitoring with quality of life and well-being showed inconclusive results [16-18] and trials exploring the impact of self-monitoring of glucose on diabetes-specific quality of life and experienced ability to perform self-care tasks are sparse[19].

World wide, two tools for glucose self-monitoring can be distinguished, which either provide continuous (SMBG) or dichotomous (SMUG) feedback.

In this study, we tested the hypotheses that self-monitoring of glucose in blood or urine with instructions affects diabetes-specific emotional distress and perceptions of self-efficacy in patients with type 2 diabetes treated with diet or oral hypoglycaemic agents.

Research design and Methods

The IN CONTROL-trial was a 3-armed randomized controlled trial performed in The Netherlands. The primary aim of the trial was to assess the effects of i) self-monitoring of blood glucose (SMBG) and ii) self-monitoring of urine glucose (SMUG) compared to iii) a control group (i.e. standardized diabetes care) in non-insulin-treated patients with type 2 diabetes. Details of the trial design and conduct are reported elsewhere [20]. In short, non-insulin using patients with type 2 diabetes, treated with diet or hypoglycaemic agents, aged between 45 and 75 years, with a diabetes duration of more than one year, an HbA1c level of 7.0% or higher and a self-reported self-monitoring frequency of maximum 3 times in the previous year were recruited from three regional diabetes care systems (total number of 6462 T2DM patients not treated with insulin). All recruiting care systems deliver diabetes care according to the most recent standard of the Dutch college of General Practitioners [21]. All patients are annually invited for a visit with a diabetes nurse and a dietician, additional to the care of their general practitioner (GP). In these visits patients are medically reviewed and provided with structured information and education involving diabetes, glucose control, (self) management and tailored advice. The Medical Ethical Committee of the VU University Medical Center Amsterdam approved the study design and protocol.

Outcome measures

The primary and pre-designated outcome measures were between groups change in diabetes-specific emotional distress and self-efficacy after 12 months. Secondary outcomes were changes in patient treatment satisfaction and depressive symptoms All patients were followed-up 4 and 12 months after baseline. Self-administered questionnaires, including variables on age, gender, diabetes duration, marital status and level of education were completed at baseline, 4 and 12 months.

Diabetes-specific distress was assessed using the Dutch validated version of the Problem Areas In Diabetes scale (PAID) [2;3;22]. This widely used 20-item self-report measure identifies diabetes-specific emotional distress, has a high internal consistency and is sensitive to change [23]. The measure consists of four sub-dimensions: Diabetes-related emotional problems (12 items), Treatment-related emotional problems (3 items), Food-related problems (3 items) and Social support-related problems (2 items). Items range from 'no problem at all' (0 points) to 'a very serious problem' (4 points). Scores were transformed to a 0-100 scale, with a cut-off score at 40, indicating seriously elevated emotional distress. Separate scores can be calculated for the sub-dimensions.

Self-efficacy was assessed by the Confidence In Diabetes Self-care questionnaire (CIDS-2) [24;25], a 20-item scale designed to assess the perceived ability to perform self-care tasks in patients with type 2 diabetes. Scores were transformed to a 0–100 scale, with higher scores indicating higher diabetes self-efficacy. Low self-efficacy was defined as a CIDS-2 score less than 71.5 points, based on Van der Ven et al (2003) [24]. Scores for items of the PAID scales and the CIDS-2 scale were only calculated when at least half of the items were present [26].

Patient treatment satisfaction was assessed by the Diabetes Treatment Satisfaction Questionnaire (DTSQ) [27]. Depression was assessed using the Patient Health Questionnaire-9 (PHQ-9) on a continuous scale [28]. Cut off point for depression was 10 points or higher.

Compliance to the self-monitoring frequency was measured using glucose diaries and glucose meter readings. Changes in prescribed glucose lowering medications were registered at follow-up and categorised as changed (any change in doses, or prescribed medication) or not changed. Patient opinions regarding skills and importance of self-monitoring were assessed at baseline and 8 weeks. Items are rated on a five-point Likert scale (0-4), ranging from 'strongly disagree' (0 points) to 'strongly agree' (4 points).

Randomisation

Computerized randomisation was used to allocate patients, who had given written informed consent, into one of the trial arms (Random Allocation Software v 1.0.0). We hypothesised that oral hypoglycaemic treatments likely to cause

hypoglycaemia (e.g. sulfonyl-urea) might modify effects on experienced levels of distress and self-efficacy. Therefore randomisation was pre-stratified by treatment. The study research manager, who was not involved in patient care, recruitment or data analyses, independently allocated patients to their intervention. Intervention allocation was concealed for laboratory staff.

Interventions

Qualified research assistants trained patients in the SMBG and SMUG group in performing and interpreting SMBG or SMUG. This included knowledge when additional tests are needed, and knowledge of which lifestyle factors can influence glucose levels. To increase understanding, patients were provided with stepwise instructions when to perform and how to interpret self-monitoring results and what actions to take. These instructions included prompts designed to provide positive feedback regardless, of the self-monitoring result [29]. Thus, it emphasized that self-monitoring results are not good or bad but in or out of range. The acquired skills in self-monitoring were checked and if necessary corrected in a control visit. Furthermore, patients were stimulated to contact their GP or nurse practitioner if they were uncertain or had questions regarding the results. Patients in the SMBG group were all provided with a blood glucose meter (LifeScan OneTouch® Ultra®2) and were asked to perform three pre-prandial and three post-prandial measurements a day on two separate days each week. Patients in the SMUG group were asked to test their urine (Urispec™ plus) on two separate days each week after dinner. Patients in both intervention groups were asked to record obtained glucose values, experienced symptoms of hypoglycaemia and comments in a study diary. To avoid extra psychological burden we allowed all patients to adjust self-monitoring frequency 'ad libitum' from eight weeks after baseline.

Changes to trial design

The trial was powered to detect a difference of 10 points in PAID scores and 6 points in CIDS-2 scores (two-sided, bonferroni corrected, $\alpha = 0.025$) between baseline and endpoint. The standard deviations of PAID and CIDS-2 change scores were initially estimated on cross-sectional validation studies in Dutch diabetes patients [2;24]. Upon analyses PAID, standard deviations were revised to

match the standard deviation of the change found in the study of Hermanns et al (2010) [30] (PAID, 15 points). Minimally 129 patients (43 per trial arm) for PAID or 228 patients (76 per trial arm) for CIDS-2 were required to achieve a minimum of 80% power for the primary hypotheses.

Statistical analyses

We used analysis of variance, adjusted for baseline values (ANCOVA) to assess differences in change between the three groups in effect of self-monitoring. Intention-to-treat (ITT) analysis were performed using data of all randomized patients in their allocated groups with baseline and at least one follow-up measurement [31;32]. When follow-up data for the 12 month measurement was not available we imputed the data by carrying the 4 months measurement forward. Additionally, we used linear mixed models (LMM), controlled for baseline levels as fixed effects and subject as random effects to explore mean differences between group means of PAID and CIDS-2 scores over a 12 months course. Effect modification by oral hypoglycaemic treatments likely to cause hypoglycaemia was tested with an interaction term (critical significant value $p<0.10$). In the case effect modification was present, outcomes were presented pre-stratified by treatment. Furthermore, we estimated the effect of the interventions in subgroups defined by complying with a monitoring frequency of at least 80% of what was requested in the first eight weeks, duration of diabetes and baseline glycaemic control. All analyses were performed in SPSS version 15.0.

Results

Figure 1 shows the flow of patients recruited, randomised and analysed. Between July 2008 and January 2009, 527 patients were asked to participate in the study. 183 patients did not meet the inclusion criteria (of which 148 had frequent access to a glucose meter), 76 patients gave a specific reason not to participate (i.e. time constraints, not feeling the need to monitor) and 87 patients declined to participate without giving reasons. The remaining 181 patients were randomized to the SMBG group (n=60), SMUG group (n=59) and to the control group (n=62) (Figure 1). Of those, 2 patients (control) died of events not related to the intervention and 13 patients were lost-to-follow-up

(SMBG=3; SMUG=6; control=4). Thirty-one patients did not persist monitoring (SMBG=8; SMUG=17) or decided to discontinue the study (control=6). Effort was made to receive completed questionnaires at follow-up, regardless of the decision to discontinue the study. Reasons for discontinuation were mostly related to time constraints. Questionnaires were completed at baseline and at least one follow-up by 53 (88.3%) patients in the SMBG group, 43 (72.8%) in the SMUG group and 55 (88.7%) in the control group. Hence, data of 151 patients was used for the analyses. Exploratory analyses of patients returning questionnaires and those who did not showed that more patients randomised in the SMUG group did not return questionnaires after 4 or 12 month (p=0.03).
At baseline, levels of distress differed statistically significant between SMBG and SMUG (p=0.01) and for self-efficacy between SMUG and control (p=0.02). Though not significantly different, slightly more female patients were included in the SMUG group. Further, no other differences at baseline, including HbA1c and prescribed oral medications, were seen between the three groups (Table 1).

Primary outcomes

Table 2 shows the mean scores and changes in PAID and CIDS-2 between baseline and 12 months. All three groups showed a small increase in PAID-total scores after 4 months, which, after 12 months, subsided in the SMBG and SMUG groups, and decreased in the control group. At 12 months no significant differences between the intervention and control groups were seen for changes in PAID-total scores (SMBG vs. control, p=0.07; SMUG vs. control, p=0.59) (Table 2). Mean differences between groups over time, corrected for the preceding measurement (LMM) are presented in Figure 2 (SMBG vs. control, mean difference = 2.56 points 95% CI -0.12 to 5.24; SMUG vs. control, mean difference = 0.81 95% CI -2.10 to 3.72). Analyses of PAID-sub-dimensions revealed a decrease in "diabetes related emotional problems" in the control group compared to SMBG and resulted in a small significant difference between these groups (p=0.05; mean difference corrected for baseline value = 2.95 points 95% CI 0.01 to 5.90). No other significant differences for sub-dimensions between groups were seen.

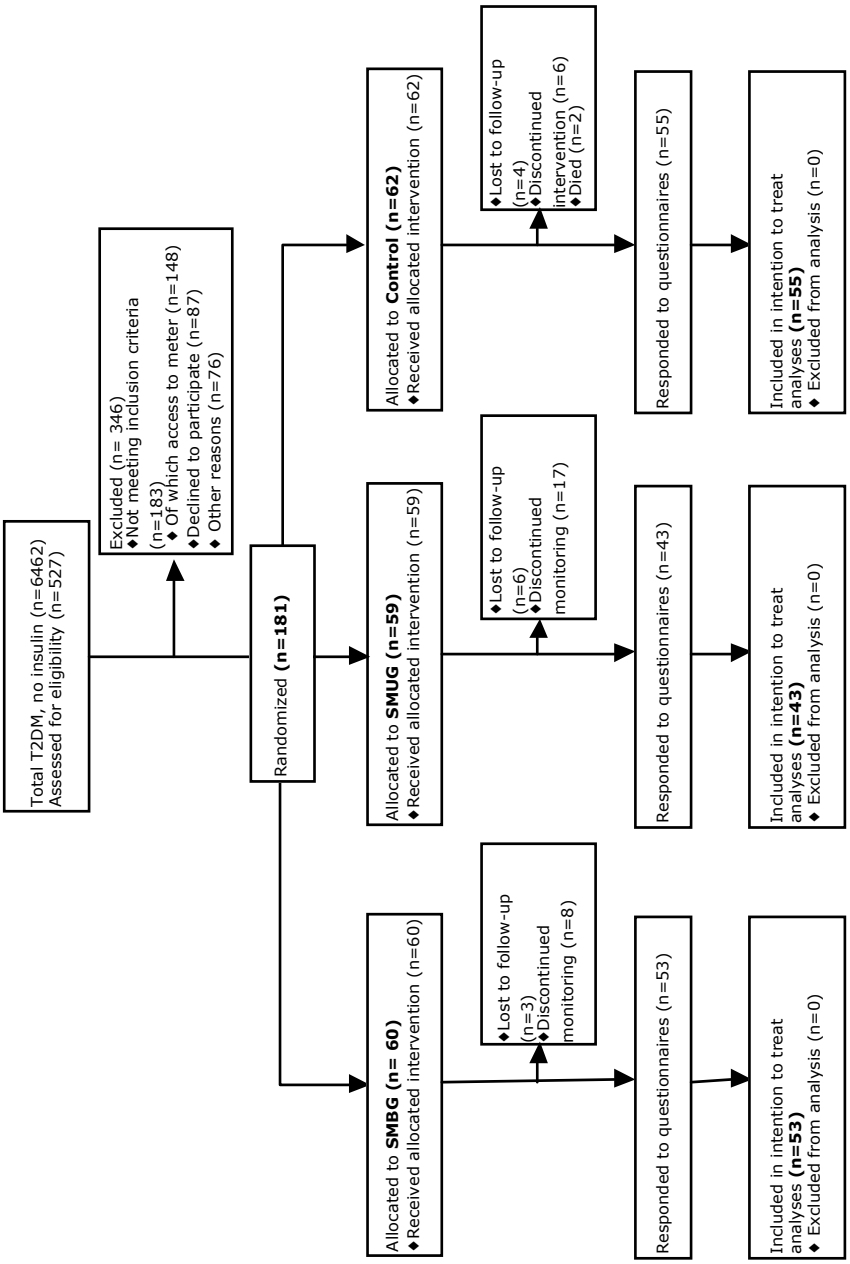

Figure 1. Flow of patients

The CIDS-2 score of patients in both SMBG and SMUG groups decreased after 4 months and then remained at the same level, whereas the control group marginally changed from baseline to 12 months. No significant differences between the SMBG, SMUG and control group were seen for changes in CIDS-2 after 12 months (SMBG vs. control, p=0.97; SMUG vs. control, p=0.28).

Table 1. Characteristics of patients with non-insulin treated type 2 diabetes at baseline, by randomisation group

A. Baseline characteristics

		SMBG n=60	SMUG n=59	Control n=62
Mean (SD) age (years)		60.8 (7.5)	62.7 (7.7)	61.2 (8.1)
Gender	*Male*	43 (71.7)	35 (59.3)	42 (67.7)
Median (q1 to q3) diabetes duration (years)		6 (3 to 8)	7 (3 to 9)	7 (4 to 9)
Mean (SD) Body-mass index (kg/m^2)		31.8 (4.8)	30.3 (4.4)	31.7 (7.5)
Mean (SD) HbA1c (%)		7.5 (0.5)	7.7 (1.0)	7.4 (0.6)
Marital status	*Living together/ married*	40 (67.8)	42 (75.0)	44 (72.1)
Education	*Elementary school or less*	4 (6.9)	9 (17.0)	10 (16.4)
	Secondary or vocational school	49 (84.5)	39 (73.6)	43 (70.5)
	Professional education or university	5 (8.6)	5 (9.4)	8 (13.1)
Job status	*Unemployed or pension*	34 (56.7)	33 (55.9)	35 (56.5)
Diabetes medication	*Non-sulphonyl urea*	30 (50.0)	30 (50.8)	28 (45.2)
	Sulphonyl urea	30 (50.0)	29 (49.2)	34 (54.8)
Diabetes medication	*Diet*	2 (3.3)	5 (8.5)	0 (0.0)
	Monotherapy	31 (51.7)	25 (42.4)	29 (46.8)
	Combined therapy	27 (45.0)	29 (49.2)	33 (53.2)

B. Characteristics of responders and non-responders to questionnaires at follow-up

		Returning n=151	Not returning n=30	*P*-value
Mean (SD) age (years)		61.8 (7.6)	60.4 (8.3)	0.38
Gender	*Male*	98 (64.9)	20 (71.4)	0.50
Randomisation group	*SMBG*	53 (35.1)	6 (21.4)	0.03
	SMUG	43 (28.5)	17 (53.6)	
	Control	55 (36.4)	7 (25.0)	
Mean (SD) HbA1c (%)		7.5 (0.7)	7.7 (0.7)	0.27
Median (q1 to q3) diabetes duration (years)		5 (3 to 8)	7 (2 to 9)	0.51

Values are numbers (%) unless stated otherwise.

In addition, no significant mean differences (LMM) in CIDS-2 scores between groups over 12 months were seen (SMBG vs. control: mean difference = 0.49 points, 95% CI -2.65 to 3.64; SMUG vs. control, mean difference = -1.43 points, 95% CI -4.95 to 2.09) (Figure 2). For both PAID and CIDS-2 no effect modification by treatment (SU) was seen between groups (p for interaction ≥0.26).

Secondary outcomes & subgroups

No statistically significant differences in change after 12 months between the intervention groups and control group were found for treatment satisfaction (DTSQ) and status of depression (PHQ-9) (Table 2). Changes in prescribed diabetes medication were not different between groups after 4 months (p=0.07) and 12 months (p=0.36). In the first eight weeks 33 (55.0%) patients in the SMBG group and 30 (52.5%) patients in the SMUG group performed a minimum of 80% of the recommended minimal self-monitoring frequency. In the subsequent eight weeks 30 (50.0%) patients in the SMBG group and 28 (47.5%) patients in the SMUG group continued self-monitoring with at least 80% of the recommended frequency. Total-PAID scores after 12 months in a subgroup defined by baseline HbA1c ≤ 7.5% increased in the SMBG-group and decreased in the control group. This resulted in a significant between group difference in total-PAID scores (SMBG vs. control; p=0.04, mean difference corrected for baseline =5.50 95% CI 0.16 to 10.83) (Table 3). No other significant differences were seen for subgroups specified by HbA1c, duration of diabetes and 80% compliance to the protocol in the first eight weeks.

Patient opinions

At baseline 80% of the participants in the SMBG group and 70% of the SMUG group considered self-monitoring of glucose in blood or urine respectively, as very important. After eight weeks this decreased to 73% and 57%, respectively. The majority of patients in the SMBG and SMUG groups reported at baseline they had adequate skills to perform self-monitoring (90% in both groups). After eight weeks, reported adequate skills remained high (SMBG group 84%; SMUG group 79%).

Table 2. Changes in mean scores (SD) in distress, self-efficacy, treatment satisfaction and depression between baseline and 12 months in non-insulin treated type 2 diabetes patients, by randomisation group

	Range		SMBG	SMUG	Control	*P*-value for difference	*P*-value for difference	*P*-value for difference
			n=53	n=43	n=55	SMBG vs. Control	SMUG vs. Control	SMBG vs. Control
Problem Areas in Distress (PAID)	0 to 100	Baseline	14.19 (14.7)	6.66 (6.5)	9.13 (11.0)			
		4 months	15.11 (17.0)	8.99 (9.6)	10.25 (11.3)			
		12 months	14.23 (15.1)	7.69 (10.1)	7.92 (9.0)			
		change 0-12	0.04 (14.8)	1.03 (8.0)	-1.21 (10.9)	0.07	0.59	0.38
Confidence in Diabetes Scale (CIDS-2)	0 to 100	Baseline	80.90 (10.2)	84.39 (9.8)	78.11 (15.1)			
		4 months	78.98 (12.2)	79.78 (10.3)	78.15 (14.1)			
		12 months	79.35 (12.2)	78.95 (15.4)	77.96 (12.2)			
		change 0-12	-1.55 (10.3)	-5.44 (11.9)	-0.14 (13.1)	0.95	0.28	0.16
Diabetes Treatment Satisfaction Questionnaire (DTSQ)	0 to 36	Baseline	27.56 (6.3)	30.98 (4.1)	29.85 (4.6)			
		4 months	27.29 (5.8)	28.24 (5.8)	29.70 (4.3)			
		12 months	28.79 (5.4)	28.95 (6.7)	30.00 (4.0)			
		change 0-12	1.23 (6.7)	-2.03 (6.2)	0.15 (4.2)	0.79	0.15	0.24
Patient Health Questionnaire (PHQ-9)	0 to 27	Baseline	4.5 (4.4)	2.59 (3.4)	3.61 (5.1)			
		4 months	4.64 (4.5)	2.69 (2.3)	3.68 (5.0)			
		12 months	4.15 (4.6)	3.12 (3.7)	3.12 (4.7)			
		change 0-12	-0.35 (2.8)	0.53 (2.0)	-0.49 (3.2)	0.54	0.15	0.25

Table 3. Change in mean scores (SD) in distress and self-efficacy between baseline and 12 months by subgroups of non-insulin treated type 2 diabetes patients

Duration of diabetes			SMBG (n=53)	n	SMUG (n=43)	n	Control (n=55)	n	P value for difference SMBG vs. Control	P value for difference SMUG vs. Control	P value for difference SMBG vs. SMUG
≤ 7 years	***PAID total score***	Baseline	13.40 (14.6)	36	6.59 (5.2)	31	9.04 (10.7)	33			
		12 months	12.84 (15.2)		8.55 (10.7)		7.25 (8.0)				
		Change 0-12	-0.56 (15.0)		1.96 (8.8)		-1.79 (9.9)		0.19	0.21	0.91
> 7 years	***PAID total score***	Baseline	16.08 (15.3)	15	6.86 (9.5)	11	9.27 (11.7)	22			
		12 months	17.58 (14.7)		5.26 (8.1)		8.93 (10.4)				
		Change 0-12	1.50 (14.7)		-1.60 (4.9)		-0.34 (13.2)		0.14	0.41	0.11
≤ 7 years	***Confidence in Diabetes Scale (CIDS-2)***	Baseline	81.37 (10.6)	37	85.68 (9.8)	31	75.28 (17.6)	27			
		12 months	81.05 (12.2)		80.15 (14.6)		76.05 (13.2)				
		Change 0-12	-0.32 (11.1)		-5.53 (10.9)		0.77 (14.2)		0.49	0.51	0.12
> 7 years	***Confidence in Diabetes Scale (CIDS-2)***	Baseline	79.75 (9.6)	15	80.41 (9.1)	10	82.35 (9.4)	18			
		12 months	75.17 (11.7)		75.26 (18.1)		80.83 (10.2)				
		Change 0-12	-4.58 (7.1)		-5.15 (15.5)		-1.52 (11.6)		0.23	0.38	0.91

Table 3. –continued

Baseline HbA1c (%)			SMBG (n=53)	n	SMUG (n=43)	n	Control (n=55)	n	P value for difference SMBG vs. Control	P value for difference SMUG vs. Control	P value for difference SMBG vs. SMUG
≤ 7.5	***PAID total score***	Baseline	13.34 (11.1)	33	6.39 (6.8)	32	9.09 (11.7)	42			
		12 months	14.77 (16.8)		6.89 (8.4)		7.00 (8.4)				
		Change 0-12	1.43 (14.1)		0.50 (6.5)		-2.09 11.0)		0.04	0.56	0.48
> 7.5	***PAID total score***	Baseline	15.75 (20.1)	18	7.53 (5.5)	10	9.25 (8.6)	13			
		12 months	13.24 (11.6)		10.25 (14.6)		10.88 (10.5)				
		Change 0-12	-2.51 (16.2)		2.72 (11.9)		1.63 (10.4)		1.00	0.88	0.96
≤ 7.5	***Confidence in Diabetes Scale (CIDS-2)***	Baseline	80.25 (9.6)	33	85.00 (10.3)	30	76.73 (15.9)	35			
		12 months	78.82 (11.1)		80.73 (13.9)		77.97 (11.6)				
		Change 0-12	-1.43 (10.5)		-4.27 (10.9)		1.24 (13.7)		0.81	0.62	0.59
> 7.5	***Confidence in Diabetes Scale (CIDS-2)***	Baseline	82.04 (11.4)	19	82.74 (8.4)	11	82.93 (11.7)	10			
		12 months	80.26 (14.3)		74.10 (18.8)		78.28 (14.9)				
		Change 0-12	-1.78 (10.1)		-8.64 (14.6)		-4.65 (9.8)		0.49	0.49	0.15

Table 3. –continued

Compliance to self-monitoring protocol			SMBG (n=53)	n	SMUG (n=43)	n	Control (n=55)	n	P value for difference SMBG vs. Control	P value for difference SMUG vs. Control	P value for difference SMBG vs. SMUG
Compliant	***PAID total score***	Baseline	14.28 (16.0)	31	6.69 (6.7)	29	9.13 (11.0)	55			
		12 months	11.32 (11.6)		7.20 (9.6)		7.92 (9.0)				
		Change 0-12	-2.96 (11.2)		0.51 (8.1)		-1.21 (10.9)		0.55	0.87	0.96
Compliant	***Confidence in Diabetes Scale (CIDS-2)***	Baseline	79.90 (10.6)	32	85.30 (9.8)	29	78.11 (15.1)	45			
		12 months	80.58 (12.5)		79.68 (13.4)		77.96 (12.2)				
		Change 0-12	0.68 (10.9)		-5.62 (10.0)		-0.15 (13.1)		0.48	0.39	0.68

Discussion

No significant changes in diabetes-specific distress were found after 12 months in moderately controlled non-insulin treated type 2 diabetes patients who used self-monitoring of glucose in blood or urine for a period of 12 months, compared to control. There were no indications that self-monitoring increased or decreased self-efficacy compared to control. In addition, no evidence was found for an effect of self-monitoring on depressive symptoms and treatment satisfaction. Furthermore, there were no differences in outcome measures between self-monitoring of blood glucose and self-monitoring of urine glucose.

Strengths and limitations of the study

To the best of our knowledge, this is the first study that investigated the effects of self-monitoring of glucose on diabetes-specific emotional distress as a primary outcome measure. The present trial had a sound theoretical and methodological base and addressed critiques on outcome measures, internal and external validity of former studies assessing the effectiveness of self-monitoring [10;12;33]. The use of structured care systems providing standardised diabetes education to all patients minimised the occurrence of co-interventions and thus, made it an ideal setting to explore the impact of self-monitoring on distress and self-efficacy. In addition, providing a standard training in self-monitoring in combination with stepwise instructions how to interpret and react on glucose measurements, a small loss to follow-up (5.5%) and a high response to questionnaires (78% after 4 months; 74% after 12 months) contributed to an adequate internal validity. Our trial was grounded in a commonly used theoretical framework that views patients as 'active problem-solvers' [13;14]. Furthermore, interpretations and actions arising from self-monitoring feedback were standardized and carefully offered by skilled research assistants, diabetes nurses and general practitioners. Despite all efforts, no significant and clinical relevant between groups differences in distress resulting from self-monitoring of glucose were noticed.

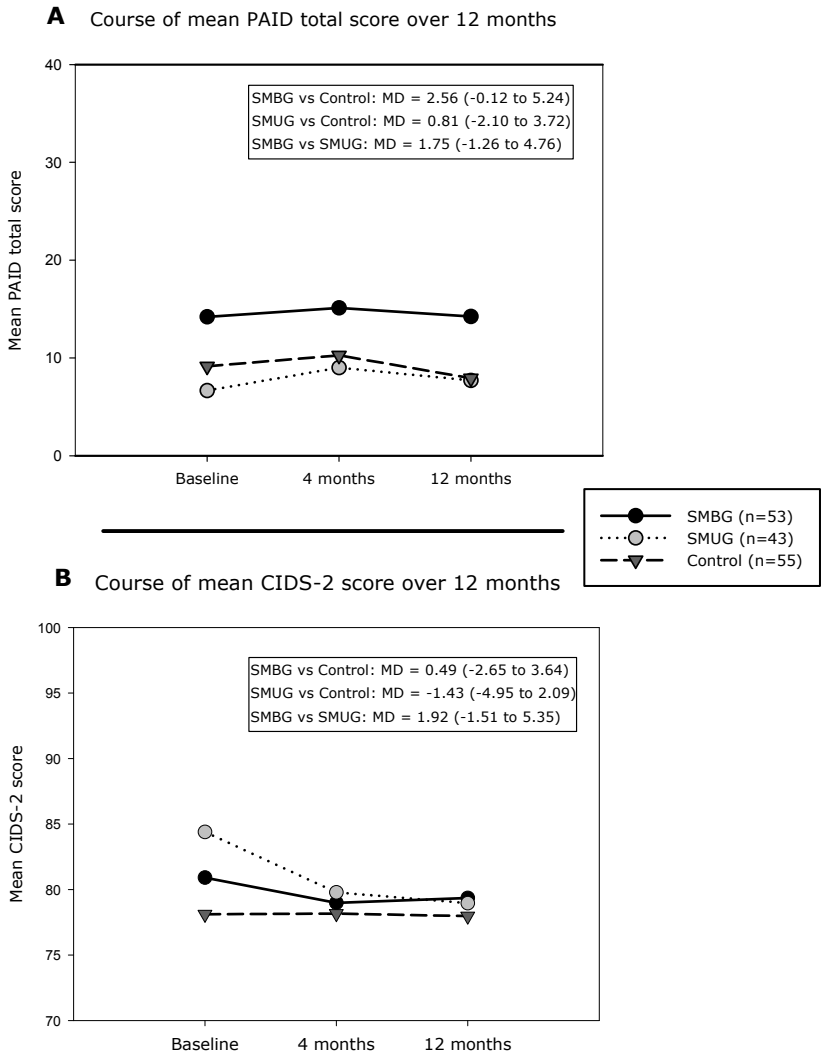

Figure 2. Mean courses of (A) PAID and (B) CIDS-2 over 12 months in patients with non-insulin treated type 2 diabetes, by randomisationgroup (MD= mean difference (95% Confidence Interval))

We made major efforts in recruitment strategies. Nevertheless, we did not meet the initially set recruitment target of 600 patients [20]. The main reason for this was an underestimation of patients in the target region that had access to a glucose meter and made frequent use of it. Exchanging the cross-sectionally based estimations of population standard deviation for an estimation of the standard deviation of the change from a recent study [30] and the present study sample, showed that including 43 patients in each group was sufficient to detect clinically relevant changes in distress with 80% power. However, with this number of patients the study was not powered to perform stratified analysis by oral hypoglycaemic agents likely to cause hypoglycaemia.

The high rate of patients in the SMUG group discontinuing monitoring suggests the possibility of selective drop-out due to intervention. Qualitative research has indicated that patients believe SMUG is less convenient and less accurate compared to SMBG, which may have enforced negative patient attitudes regarding SMUG [34]. According to our responder analysis, there were no differences in patient characteristics at baseline between patients responding and not responding to questionnaires.

Patients in all groups experienced relatively low levels of distress and perceived high levels of self-efficacy at baseline, leaving little potential for improvement. In addition, the mean levels of distress in patients in the SMUG and the control group at baseline approximated the amount minimally needed to detect a clinically important improvement, which indicates the presence of a floor effect.

Comparison with other studies

Previous cross-sectional studies exploring the impact of self-monitoring of glucose have suggested that SMBG in non-insulin treated type 2 diabetes patients is associated with greater diabetes related burden, worries and distress [18;35]. In contrast to our study, in these studies patients did not receive diabetes education, specific training in self-monitoring or ongoing motivation and support. Further, due to the nature of cross-sectional studies predication of causality cannot be proven.

Qualitative studies suggest that patients using SMBG may experience more feelings of control over their diabetes self-management [36;37]. In our study, no

different change in self-efficacy between both intervention and control groups was noticed. A possible explanation for the lack of consistency between these findings and the present is that discordance may exist between what patients feel they are able to do and what they actually do.

In our design we aimed to prevent additional development of emotional distress by incorporating the possibility to independently adjust the requested self-monitoring frequency to one patient's 'feel comfortable with' from eight weeks after baseline. The option to individually alter self-monitoring frequency is grounded in the theoretical framework since it suggests that feedback from self-monitoring and evaluation of taken (re)actions primarily accounts to the success of self-monitoring, independent of frequency. In our study self-monitoring frequency decreased in both intervention groups starting from eight weeks after baseline. This decrease in frequency was expected, because an eight-week period is sufficient to familiarize with the process of monitoring and receiving feedback and to experience how lifestyle factors can influence glucose levels.

Our hypothesis that self-monitoring empowers patients by its feedback, leading to changes in diabetes-specific distress and self-efficacy was not proven. The main quality of SMBG is that it delivers feedback throughout the continuous range for normo-, hypo- and hyperglycaemic results, whereas feedback from SMUG only delivers dichotomous information whether or not results are hypoglycaemic. Nevertheless, in our study, feedback from either SMBG or SMUG did not affected distress and self-efficacy differently.

Indications that self-monitoring of glucose may lead to worries and frustration, were not confirmed in our trial. Our results showed that self-monitoring of glucose did not increase symptoms of depression in non-insulin treated type 2 diabetes patients.

Implications for practice and future research

The usefulness of long-term self-monitoring of glucose in blood or urine for glycaemic control in moderately controlled and well-instructed type 2 diabetes patients, who are not treated with insulin, remains an important topic. Our results imply that, in contrast to recent concerns, routine self-monitoring in blood or urine did not induce diabetes-specific emotional distress for this specific patient group. With respect to the lingering discussion on the glycaemic effect of

self-monitoring, it seems as if self-monitoring interventions as they are currently implemented do not provoke changes in diabetes-specific distress and self-efficacy. Therefore, future studies should focus on how self-monitoring influences determinants within the pathway of self-regulation responsible for changes in diabetes-specific emotional and biochemical outcomes.

Self-monitoring of glucose is a tool advocated world wide and used by educators to help patients improve their self-management. Yet at present, there is insufficient evidence that self-monitoring of glucose in moderately controlled non-insulin treated patients with type 2 diabetes offers advantages in diabetes-specific emotional distress or self-efficacy. When adding the present results to the existing lack of consensus on glycaemic benefits and the large management costs [38], it appears that the clinical relevance of self-monitoring of glucose in this category of patients is small.

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